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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,139	04/13/2004	John C. Oslund	ev31010USD1	4537
9561	7590	07/28/2005	EXAMINER	
POPOVICH, WILES & O'CONNELL, PA 650 THIRD AVENUE SOUTH SUITE 600 MINNEAPOLIS, MN 55402			EREZO, DARWIN P	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,139

Applicant(s)

OSLUND ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,29-31,56-59 and 61-70 is/are pending in the application.
- 4a) Of the above claim(s) 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19,30,31,56-59 and 61-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/13/04; 9/03/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 5/16/05 is acknowledged.
2. Claim 19 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/16/05.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-13, 16-19, 30, 31, 56-59 and 61-70 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,814,064 to Daniel et al.

Daniel teaches a distal protection device comprising a filter basket **18** having closed distal end and an open proximal end; a self expanding radial member **20** associated with the filter basket in proximity to the proximal end thereof, said member being adapted to maintain the proximal end of the filter basket in an open configuration; wherein an opposite end of the filter basket is mounted on a guidewire **14**; wherein the filter basket is in a shape of a windsock, wherein the filter basket includes a tube through which the guidewire extends (the filter basket is configured as a tube in which

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the guidewire extends therethrough); wherein said radial member **20** comprises a loop (embodiment shown in Fig. 8); wherein the radial member is formed as a "C", "J" or spiral configuration (depending on the portion of radial member shown in Fig. 1); wherein the expandable member is formed from nitinol (col. 9, line 53); wherein the loop in its expanded state defines a lane that is substantially perpendicular (90 degrees) to the guidewire (Fig. 1); wherein the filter basket and loop are adapted to be collapsed to fit into a small diameter delivery catheter (Fig. 2); wherein the end of the filter basket that is free floating cooperates with the guidewire in a manner which allow the free floating end to move rotationally and axially along the guidewire; wherein the device comprises alignment maintenance means for precluding rotation of the loop relative to the proximal end of the filter basket (since the loop can be attached to the guidewire at the proximal end); wherein the maintenance means can comprise a plurality of tethers (embodiment shown in Fig. 6, tethers **46**);

Daniel also teaches a method of capturing debris formed during a medical procedure in human vasculature, comprising the steps of inserting a catheter **120** containing a distal protection device **118** in collapsed configuration into human vasculature; deploying the distal protection device on a distal side of the vasculature affected by a medical procedure; maintaining the distal protection device generally concentrically within the vasculature; and capturing debris produced by the medical procedure within the distal protection device (Fig. 12)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. ('064) as recited above, and in view of US 6,001,118 to Daniel et al. ('118).

The '064 reference teaches all the limitations of the claims except for the device having radiopaque material. However, the '118 reference teaches a distal protection device that comprises radiopaque material (col. 14, lines 60-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add radiopaque material to the '064 reference because it allows a practitioner to monitor the position of the device within the vessel using a scope.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-18, 30, 31, 62-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-32 of U.S. Patent No. 6,740,061. For double patenting to exist between the rejected claims and the patented claims, it must be determined that the rejected claims are not patentably distinct from the patented claims. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and the recited patented claims and, if so, whether those differences render the claims patentably distinct.

Claim 1 recites a distal protection device comprising a filter basket and a self-expanding radial member.

It is clear that all the elements of claim 1 are to be found in claim 17 of the patent. The difference between claim 1 of the application and claim 17 of the patent lies in the fact that the patent claim includes additional elements and is thus much more specific. Thus the invention of claim 17 of the patent is in effect a "species" of the "generic" invention of claim 1 of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 1 of the application is anticipated by claim 17 of the patent, it is not patentably distinct.

As to claim 2 of the application, see claim 18 of the patent.

As to claim 3 of the application, see claim 19 of the patent.

As to claims 4, 7 and 30 of the application, see claim 20 of the patent.

As to claims 5, 8, 31 and 62-70 of the application, see claim 22 of the patent.

As to claims 6 and 9 of the application, see claim 23 of the patent.

As to claim 10 of the application, see claim 24 of the patent.

As to claim 11 of the application, see claim 25 of the patent.

As to claim 12 of the application, see claim 26 of the patent.

As to claim 13 of the application, see claim 27 of the patent.

As to claim 14 of the application, see claim 28 of the patent.

As to claim 15 of the application, see claim 29 of the patent.

As to claim 16 of the application, see claim 30 of the patent.

As to claim 17 of the application, see claim 31 of the patent.

As to claim 18 of the application, see claim 32 of the patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER